# Diagnostic Performance Evaluation of Three COVID-19 Rapid Immunochromatographic Test Kits on Clinical Samples Tested by rRT-PCR.

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**Abstract**

**Background**: COVID-19 has imposed significant burden on healthcare systems worldwide. The need for simple, rapid, and affordable diagnostic tests to support the existing costly and demanding polymerase chain reaction (PCR) assay is very necessary. **Methods:** This study evaluated the performance characteristics of three (3) COVID-19 rapid antigen test kits: DG Rapid, SD Rapid and SS Rapid. They were compared with the gold standard real-time reverse transcriptase- PCR (rRT-PCR) for the detection of SARS-CoV-2 nucleocapsid antigen in 75 archived samples. **Results:** Of the 75 samples tested, 38 (50.7%) were positive and 37 (49.3%) were negative for SARS-CoV-2 RNA by rRT-PCR assay. No false positive was recorded. The DG Rapid kit detected 30 (78.9%) true positives and 8 (21.1%) false negatives. SD Rapid kit detected 28 (73.7%) true positives and 10 (26.3%) false negatives, while the SS Rapid kit detected 19 (50.0%) true positives and 19 (50.0%) false negatives. Specificity of each test kit was 100% (CI 95%), but the sensitivity of the DG Rapid, SD Rapid, and SS Rapid kits was 79%, 74%, and 50% (CI 95%), respectively. Higher sensitivities among samples with Ct values <29.99 were recorded for each kit. Also, the DG Rapid kit demonstrated 79% excellent agreement with rRT-PCR, while the SD Rapid and SS Rapid kits demonstrated good agreement with rRT-PCR with 73% and 50% Cohen's kappa values, respectively. **Conclusion:** The study suggests that DG Rapid and SD Rapid kits are reliable alternatives to rRT-PCR for the detection of SARS-CoV-2 infection, especially in resource-limited settings like Ghana.

*Title:*

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**ABSTRACT**

**Background** : COVID-19 has imposed significant burden on healthcare systems worldwide. The need for simple, rapid, and affordable diagnostic tests to support the existing costly and demanding polymerase chain reaction (PCR) assay is very necessary.

**Methods:** This study evaluated the performance characteristics of three (3) COVID-19 rapid antigen test kits: DG Rapid, SD Rapid and SS Rapid. They were compared with the gold standard real-time reverse transcriptase- PCR (rRT-PCR) for the detection of SARS-CoV-2 nucleocapsid antigen in 75 archived samples.

**Results:** Of the 75 samples tested, 38 (50.7%) were positive and 37 (49.3%) were negative for SARS-CoV-2 RNA by rRT-PCR assay. No false positive was recorded. The DG Rapid kit detected 30 (78.9%) true positives and 8 (21.1%) false negatives. SD Rapid kit detected 28 (73.7%) true positives and 10 (26.3%) false negatives, while the SS Rapid kit detected 19 (50.0%) true positives and 19 (50.0%) false negatives. Specificity of each test kit was 100% (CI 95%), but the sensitivity of the DG Rapid, SD Rapid, and SS Rapid kits was 79%, 74%, and 50% (CI 95%), respectively. Higher sensitivities among samples with Ct values <29.99 were recorded for each kit. Also, the DG Rapid kit demonstrated 79% excellent agreement with rRT-PCR, while the SD Rapid and SS Rapid kits demonstrated good agreement with rRT-PCR with 73% and 50% Cohen's kappa values, respectively.

**Conclusion:** The study suggests that DG Rapid and SD Rapid kits are reliable alternatives to rRT-PCR for the detection of SARS-CoV-2 infection, especially in resource-limited settings like Ghana.

**Keywords:** COVID-19, SARS-CoV-2, polymerase chain reaction (PCR), rapid antigen test kits.

**Background**

The World Health Organization (WHO) declared the outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 or COVID-19) as a pandemic on 12th March 2020 (1). The pandemic which began after a cluster of cases of pneumonia with unknown etiology was reported in the Hubei province of Wuhan,

China (2,3) The novel coronavirus was identified as the etiological agent that was spreading rapidly to other cities in China and other countries worldwide (4). Globally, the number of confirmed cases and deaths reported to the World Health Organization (WHO) as of 7$^{th}$ November 2022 are 632,895,390 and 6,596,852, respectively (5). In Ghana, the first confirmed case was recorded on 12$^{th}$ March 2020 (6), and the number of confirmed cases reported to the World Health Organization from all regions of the country stood at 170,972, with 1,461 deaths as of 7$^{th}$ November 2022 (5).

In the heat of the pandemic, various rRT-PCR laboratories were set up, and other existing laboratories were revamped to increase the preparedness of the country in terms of testing suspected cases (7). However, rRT-PCR is costly, time consuming and requires specially trained personnel to execute (8). The rapid immunochromatographic antigen test tries to fulfill this task and may be used directly and instantly, offering results within a few minutes. This permits speedy decision making, which strongly affects clinical management outcomes (9). The aim of this study was to assess the quality performance of three (3) COVID-19 rapid antigen test kits, the DG Rapid RDT, SD Rapid RDT and SS Rapid RDT on the Ghanaian market, as the reliance on such RDTs continues to grow. The specific objectives were to determine and compare the sensitivity, specificity, and predictive values of the three antigen test kits to known rRT-PCR tested samples. Others include comparing the sensitivity, specificity, and predictive values of the test kits to the kits manufacturer's claims; contrasting the sensitivity, specificity, and predictive values of the test kits with the known Ct values obtained from rRT-PCR tested samples; and evaluating the overall agreement of these test kits against the gold standard rRT-PCR.

## Methods

### Study design, site, participants, test method and data analysis.

Study Design, Site and Archival Sample Selection Criteria

This study was an experimental retrospective study of archived CoViD-19 rRT-PCR samples. Ethical approval was sought and obtained from the University for Development Studies review board (UDS/IRB/115/22). Three packets (75pcs) each of DG Rapid, SD Rapid, and SS Rapid were randomly sampled from the Ghanaian market. The study was conducted at a Food and Drugs Authority/Health Facilities Regulatory Agency (FDA/HeFRA) registered SARS-CoV-2 rRT-PCR testing facility in the Greater Accra Region of Ghana, between June 2022 and July 2022. The eligibility criteria for this study involved using clinical samples that were previously tested for COVID-19 using the rRT-PCR technique. However, samples which are insufficient, inadequately labelled, or other sample quality issues were excluded from the study. There were no restrictions on age, gender, or ethnicity.

Sample and Data Analysis

Seventy-five (75) frozen archived nasopharyngeal samples – consisting of 38 positive and 37 negative rRT-PCR tested COVID-19 samples were obtained for the evaluation of the three (3) brands of the immunochromatographic RDT kits. The archived samples were selected using a flow chart (supplementary figure 1, SF1 ). It is worth noting that these samples were retested using rRT-PCR (the reference test, S0 ) prior to the immunochromatographic assays (the index test, S1 ). The three immunochromatographic antigen kits (i.e., DG Rapid, SD Rapid, and SS Rapid) consist of qualitative membrane-based immunoassays and detect SARS-CoV-2 nucleocapsid antigen. All assays were performed by a single operator for each brand of test kit, with two blind operators reading the results. In case of discrepancies, a third operator was consulted, especially for faint test lines. All tests were performed according to the manufacturer's instructions (10–12). The results generated were entered into Microsoft Excel-365 and analyzed using IBM SPSS Statistics version 23. A Flow chart of the method from sample selection to data analysis can be found in supplementary figure 1 (SF1)

## Results

### Detection made by the three brands of COVID-19 test kits.

**Table 1** shows the results of some quality characteristics for the three different test kits: DG Rapid, SD Rapid, and SS Rapid. The results indicate that the DG Rapid and SD Rapid groups had higher percentages of true positives (TPs) and lower percentages of false negatives (FNs) than the SS Rapid group. However, all test kits recorded a 100% true negative (TN) and zero cases of false positives (FPs), suggesting high specificity for all three kits.

**Table 1. Results distribution for TP, TN, FN, and FP**

| Test kits | True Positive n (%) | True Negative n (%) | False Negative n (%) | False Positive n (%) |
|---|---|---|---|---|
| DG Rapid | 30 (78.9) | 37 (100.0) | 8 (21.1) | 0 |
| SD Rapid | 28 (73.7) | 37 (100.0) | 10 (26.3) | 0 |
| SS Rapid | 19 (50.0) | 37 (100.0) | 19 (50.0) | 0 |

*Table 1: TP, TN, FN and FP determined in numbers and percentages among the three brands. The table displays the number of observations (n) and percentage (%) of results for each category*

*in parentheses.*

**Diagnostic performance of COVID-19 immunochromatographic rapid test (ICT) kits.**

**Table 2** presents the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy of the three different ICT kits.

The sensitivity of DG Rapid and SD Rapid was relatively high, with values of 78.9% and 73.7%, respectively, while the sensitivity of SS Rapid was lower at 50.0%. All three kits demonstrated 100.0% specificity and 100% PPV. The NPVs of DG Rapid, SD Rapid, and SS Rapid were 82.2%, 78.7%, and 66.1%, respectively.

The overall accuracy was highest for DG Rapid at 89.3%, followed by SD Rapid at 86.7%, and SS Rapid at 74.7%. These results suggest that DG Rapid and SD Rapid may be more effective than SS Rapid for detecting SARS-CoV-2 RNA.

**Table 2. Sensitivity, Specificity, PPV, NPV and Overall Accuracy of the ICT kits**

| Parameters | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) | Overall Accuracy (%) |
|---|---|---|---|---|---|
| DG Rapid | 78.9 | 100.0 | 100.0 | 82.2 | 89.3 |
| SD Rapid | 73.7 | 100.0 | 100.0 | 78.7 | 86.7 |
| SS Rapid | 50.0 | 100.0 | 100.0 | 66.1 | 74.7 |

*Table 2: Sensitivity, Specificity, PPV, NPV, and Overall Accuracy of the Kits*

**Comparison of Overall Accuracy and Cohen's kappa coefficient of the Manufacturers and the Operators**

**Table 3** presents a comparison of the overall accuracy and Cohen's kappa coefficient of three different manufacturers' ICT kits and the operators' COVID-19 immunochromatographic rapid test (ICT) kits. Overall accuracy varies with disease prevalence, and it may mislead if the study population differs from the actual population. Cohen's kappa coefficient was used as an alternative to compare the prediction performance of the ICT kits to rRT-PCR with kappa values indicating agreement levels; >75% implying excellent/total agreement, 40-75% good agreement, and <40% poor agreement with rRT-PCR.

When the manufacturers' and operators' analysis are compared, the overall accuracy and Cohen's kappa coefficient of the operators' analysis is lower than that of the manufacturers' analysis for all three kits.

Nonetheless, the results still indicate that the DG Rapid kit is the most reliable ICT kit in both manufacturers' and operators' analysis.

| Parameters | Manufacturers' Overall Accuracy (%) | Manufacturers' Cohen's kappa (%) | Operators' Overall Accuracy (% |
|---|---|---|---|
| DG Rapid | 98.8 | 97.3 | 89.3 |
| SD Rapid | 98.4 | 89.1 | 86.7 |
| SS Rapid | 99.2 | 96.5 | 74.7 |

**Table 3. Comparison of overall accuracy and Cohen's kappa coefficient of manufacturers' ICT kits and the post surveillance analysis by operators'**

*Table 3: Comparative analysis of overall accuracy and Cohen's kappa coefficient between manufacturers' ICT kits and the operators' ICT kits*

**Diagnostic Performance Characteristics of the Operators' ICT Kits Based on rRT-PCR Ct Value Categories**

To determine the diagnostic performance characteristics of the test kits in comparison with viral load, the cycle threshold (Ct) values were classified into 19.00 – 29.99, 30.00 – 34.99 and >35.00 to determine the threshold at which the test kits would have the best performance.

The results show that the DG Rapid and SD Rapid kits had higher sensitivity and Cohen's kappa coefficient than the SS Rapid kit in detecting SARS-CoV-2 across all Ct value categories. However, all three kits showed high specificity and PPV in all Ct value categories. Specifically, Cohen's kappa coefficient indicated substantial or excellent agreement between the ICT kits and rRT-PCR results at lower Ct values (19.00 - 29.99 and 30.00 - 34.99) for the DG Rapid and SD Rapid kits, but only good agreement for the SS Rapid kit. However, for Ct values >35.00, all three kits had poor agreement with rRT-PCR.

**Table 4: Diagnostic Performance Characteristics of the Operators' ICT Kits Based On rRT-PCR Ct Value Categories.**

| Test kits (N=75) | rRT-PCR Ct values | Sensitivity (%) | Sensitivity (%) | Specificity (%) | Specificity (%) | PPV (%) | NPV (%) | Overall Accuracy (%) | Co ka co (% |
|---|---|---|---|---|---|---|---|---|---|
| DG Rapid (n=24) | 19.00 - 29.99 | 91.7 | 100 | 100 | 100 | 100 | 94.9 | 96.7 | 93. |
| DG Rapid (n=7) | 30.00 - 34.99 | 85.7 | 100 | 100 | 100 | 100 | 97.4 | 97.7 | 91. |
| DG Rapid (n=7) | >35.00 | 28.6 | 100 | 100 | 100 | 100 | 88.1 | 88.6 | 40. |
| SD Rapid (n=24) | 19.00 - 29.99 | 88.9 | 100 | 100 | 100 | 100 | 92.5 | 95.3 | 90. |
| SD Rapid (n=7) | 30.00 - 34.99 | 71.4 | 100 | 100 | 100 | 100 | 94.9 | 95.5 | 80. |
| SD Rapid (n=7) | >35.00 | 28.6 | 100 | 100 | 100 | 100 | 88.1 | 88.6 | 40. |
| SS Rapid (n=24) | 19.00 - 29.99 | 58.3 | 100 | 100 | 100 | 100 | 78.7 | 83.6 | 62. |
| SS Rapid (n=7) | 30.00 - 34.99 | 57.1 | 100 | 100 | 100 | 100 | 92.5 | 93.2 | 69. |

| Test kits (N=75) | rRT-PCR Ct values | Sensitivity (%) | Sensitivity (%) | Specificity (%) | Specificity (%) | PPV (%) | NPV (%) | Overall Accuracy (%) | Co ka co (% |
|---|---|---|---|---|---|---|---|---|---|
| SS Rapid (n=7) | >35.00 | 14.3 | 100 | 100 | 100 | 100 | 86.0 | 86.4 | 21. |

*Table 4: A negative rRT-PCR is defined as having a Ct-value >40, while a positive rRT-PCR is defined as a Ct -value <40. N represents the total number of samples analyzed, while n represents only samples that tested positive. Thirty-seven (37) samples tested negative.*

**Comparison of Overall Accuracy and Cohen's kappa coefficient based on rRT-PCR Ct values for Operators' ICT Kits**

The various rRT-PCR Ct value categories were compared with the overall accuracy and Cohen's kappa coefficient to ascertain if the Ct values affected any of these diagnostic performance indicators. The results show that the DG Rapid and SD Rapid kits had higher overall accuracy and Cohen's kappa coefficient than the SS Rapid kit across all Ct value categories. The DG Rapid kit had the highest overall accuracy and Cohen's kappa coefficient for Ct values of 19.00 - 29.99 and 30.00 - 34.99, while the SD Rapid kit had the second highest overall accuracy and Cohen's kappa coefficient for the same ranges. The SS Rapid kit had the lowest overall accuracy and Cohen's kappa coefficient across all Ct value categories. However, for Ct values >35.00, all three kits recorded the lowest overall accuracy and Cohen's kappa coefficient.

| Test kits. (N=75) | rRT-PCR Ct values | Overall Accuracy (%) | Cohen's kappa coefficient (%) |
|---|---|---|---|
| DG Rapid (n=24) | 19.00 - 29.99 | 96.7 | 93.0 |
| DG Rapid (n=7) | 30.00 - 34.99 | 97.7 | 91.0 |
| DG Rapid (n=7) | >35.00 | 88.6 | 40.2 |
| SD Rapid (n=24) | 19.00 - 24.99 | 95.3 | 90.2 |
| SD Rapid (n=7) | 30.00 - 34.99 | 95.5 | 80.8 |
| SD Rapid (n=7) | >35.00 | 88.6 | 40.2 |
| SS Rapid (n=24) | 19.00 - 24.99 | 83.6 | 62.9 |
| SS Rapid (n=7) | 30.00 - 34.99 | 93.2 | 69.2 |
| SS Rapid (n=7) | >35.00 | 86.4 | 21.9 |

**Table 5. Comparison of overall accuracy and Cohen's kappa coefficient of operators' ICT kits based on rRT-PCR Ct value categories.**

*Table 5: Comparative analysis of overall accuracy and Cohen's kappa coefficient among the operators' ICT kits based on their Ct value categories. N represents the total number of samples analyzed, while n represents only samples that tested positive. Thirty-seven (37) samples tested negative.*

**Discussion**

This study evaluated the diagnostic performance characteristics of these brands of COVID-19 ICT test kits on the Ghanaian market, namely, DG Rapid (DGT), SD Rapid (SD), and SS Rapid (SS). Rapid antigen tests offer several advantages, including affordability, faster turnaround time, and the ability to diagnose patients at their point-of-care. These advantages are essential and critical, especially in resource-limited settings, where rRT-PCR testing may not be readily available. This study demonstrated that DG Rapid and SD Rapid antigen test kits performed relatively better in detecting SARS-CoV-2 than SS Rapid.

The findings for DG Rapid and SD Rapid are consistent with previous studies that have reported the effectiveness of rapid antigen tests in detecting COVID-19 (13). These studies showed a relatively lower sensitivity with SARS-CoV-2 antigen rapid diagnostic test kits (Ag-RDTs) compared to the clinical reference standard, which is the real-time reverse transcriptase- polymerase chain reaction (rRT-PCR). A recent systematic review and meta-analysis that evaluated the accuracy of commercially available SARS-CoV-2 Ag-RDTs revealed a pooled sensitivity of 71.2% (13). A sensitivity of 70% and 59% (95% CI) respectively was observed in 262 study participants in Uganda and Cameroon, respectively, using the SD Rapid RDT (14,15). In Cameroon, the RDTs' sensitivity of 59% (95% CI) increased to 69% (95% CI) when only symptomatic participants were considered. Another study conducted at a teaching hospital in northern Ghana evaluated the sensitivity of the SD Rapid RDT with 193 participants as 64% (95% CI) (16). Our study, however, found a sensitivity of 74% (95% CI) for SD Rapid RDT, which is comparable to what was observed in Uganda and Cameroon. Moreover, among the three brands, DG Rapid demonstrated a higher sensitivity of 79% (95% CI), followed by SD Rapid with 74% (95% CI). However, the SS Rapid RDT demonstrated a lower sensitivity of 50% (95% CI) compared to the other two brands. This lower sensitivity for SS Rapid may limit its usefulness as a standalone diagnostic tool, as it may lead to false negative results. False negative results may result in a delay in diagnosis, thereby increasing the risk of virus transmission. It is noteworthy that these values of sensitivity observed in our study are much below the performance reported by the manufacturers (DG Rapid, 2022; SD Rapid, 2020; SS Rapid, 2021). Possible explanations for the lower sensitivity observed could be due to factors such as variations in the batch of ICT kits used, variations in the concentration of extracted antigens, differences in processing techniques, and variations in the storage conditions of the kits, especially in the market (18).

In this study, the specificity was 100% (95% CI), which is comparable to the 100% (95% CI) stated by the manufacturers but higher than the 92% (95% CI) documented in the studies conducted in both Uganda and Cameroon. The possible explanations given for the lower specificity in these other studies were cross-reacting antibodies from previous infections or variations in environmental testing temperatures (24°C - 37°C) in the general wards and the COVID-19 isolation center where the tests were carried out (16). The high specificity exhibited by all three test kits in our study is an important attribute as it ensures that individuals without the virus are correctly identified, reducing the risk of false-positive results. False positives can lead to unwarranted quarantine, isolation, and treatment, with significant social and economic consequences.

Regarding overall accuracy, this study reported values of 89% (for DG Rapid), 87% (SD Rapid), and 75% (SS Rapid) at 95% CI for the three SARS-CoV-2 ICT kits, which are lower than the manufacturers' claims of 99%, 98%, and 99%, respectively. However, it is essential to recognize that overall accuracy can vary with disease prevalence, making it less reliable as a single summary measure of a test's validity. The prevalence-dependent nature of overall accuracy introduces challenges, leading to warnings against its use. Estimates of overall accuracy can be misleading when obtained from populations with significantly different disease prevalence from the target population where the test is intended for application (19).

To assess the agreement between the ICT kits and rRT-PCR, Cohen's kappa coefficient was employed. Specifically, it was used to determine the level of agreement between the performance of the ICT kits and rRT-PCR. Our findings indicated that only DG Rapid demonstrated excellent agreement, while SD Rapid and SS Rapid exhibited good agreement compared to rRT-PCR. This observation could be because DG Rapid demonstrated a higher sensitivity of 79% and a higher NPV of 82% compared to the other brands. Other performance indicators, specifically, specificity and PPV, were the same (100%) for all three brands and thus did not have an impact on the kappa value calculation. In a study conducted in India, Cohen's kappa calculated for SD Rapid and rRT-PCR showed a good agreement, with a Cohen's kappa of 64.4%(20). Another study conducted in Ethiopia found that a SARS-CoV-2 antigen rapid test kit and rRT-PCR had a kappa value of agreement of 73.5% which indicates good agreement between the two tests (21). While we could not find specific research articles on DG and SS Rapid kits, the evidence from the study conducted in both India and Ethiopia suggests a consistent trend of good agreement between SARS-CoV-2 antigen rapid test kits such as SD Rapid and rRT-PCR.

By convention, a lower Ct value signifies a higher viral load, while a higher Ct value suggests a lower viral load (13). All three brands demonstrated better detection limits for higher viral load (Ct values [?]29.99), which is often the case in the pre-symptomatic phase (1–3 days before the onset of symptoms) and the early symptomatic phase (during the first 5 – 7 days of illness) of SARS-CoV-2 infection (22). Conversely, they displayed less favorable detection limits for Ct values >35.00.. Consequently, the DG Rapid ICT kits exhibit a lower detection threshold when Ct values exceed 35.00, despite their excellent agreement with rRT-PCR. It is essential to acknowledge that our study utilized frozen archived nasopharyngeal samples, which may not represent the current situation accurately. The performance of these antigen test kits can be influenced by factors such as viral load and the type of specimen used for testing(13). Therefore, it is crucial to evaluate the performance of these rapid antigen test kits on fresh samples and in real-life settings.

**Conclusion**

The study findings indicate that the DG Rapid and SD Rapid kits can be considered reliable substitutes for rRT-PCR in detecting SARS-CoV-2 infection, particularly in areas with scarce resources and limited access to PCR testing. The study also indicates that these test kits exhibit a high level of sensitivity in samples with Ct values lower than 29.99, indicating that they would have good performance in patients with a high viral load (Ct values [?]29.99). These findings support the use of rapid antigen tests as an alternative diagnostic tool for COVID-19.

This study recommends a continuous quality assessment program by relevant regulatory and monitoring agencies to not allow a potential positive case to return with a false negative result. Given these findings, we also recommend a further study with a larger fresh sample size to be done on the other existing COVID-19 RDT kits on the Ghanaian market, as rRT-PCR testing is expensive and ubiquitously unavailable.

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## Declarations

### Ethical Approval

Ethical approval was obtained from the University for Development Studies Institutional Review Board (UDS/RB/115/22). Consent to use the anonymized CoViD-19 tested samples, was obtained from the appropriate authority within the FDA/HeFRA registered testing facility.

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### Availability of data and materials

The datasets used and/or analyzed during the current study are available with this submission as supplementary material/related files.

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**Conflict of Interest Statement**

Authors declare that they have no conflicts of interest.

**Author Contributions**

SB Bani and C. Obirikorang were involved in conceptualization, methodology, supervision, writing the original draft, review and editing of the final draft.

EK Amakye, S Akomeah and ENY Nyarko were involved in conceptualization, methodology, data analysis, writing of the original draft, and review and editing of the final draft.

F Bani, DND Dodoo, C Aidoo, M Fynn-Buadu, and M Adom were involved in data collection, sample analysis, software, data curation and writing - review and editing.

All the authors have read and approved the final manuscript for publication.

**Competing interests**

We, the authors of this manuscript declare that we have no competing interests.